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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,103	09/12/2003	Parminder Singh	2335-0008.22	6566
23980	7590	11/15/2006		
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C 1400 PAGE MILL ROAD PALO ALTO, CA 94304-1124				
			EXAMINER GHALI, ISIS A D	
			ART UNIT 1615	PAPER NUMBER

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/661,103

Applicant(s)

SINGH ET AL.

Examiner

Isis A. Ghali

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 22 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The prosecution of this application has been transferred from examiner David Vanik to examiner Isis Ghali.

The receipt is acknowledged of applicants' amendment filed 08/22/2006.

Claims 1-59 are pending and included in the prosecution.

**The following rejection has been overcome by virtue of applicants' amendment and remarks:**

The provisional rejection of claims 1-28, 38-59 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 7-16, 21- 61 of copending Application No. 10/359,548 ('548).

**The following new ground of rejection is necessitated by applicants' amendment:**

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment made to the claims has introduced new matter by reciting "the backing polymer having lower aqueous solubility than the water-swellaable, water-insoluble polymer". The specification as originally filed does not disclose this limitation. Paragraph 00113 disclosed that the erodible backing member erodes slower than the hydrogel composition as a whole that comprises water-swellaable, water-insoluble polymer and blend of hydrophilic polymer with complementary oligomer, and not slower than the water-swellaable, water-insoluble polymer that forms one component of the hydrogel. The specification does not disclose polymers of backing members that have aqueous solubility. On paragraph 00114 applicants disclosed that in case Eudragit polymer is used for both the backing and water-swellaable, water-insoluble polymer, then Eudragit with lower solubility is selected for the backing and Eudragit of higher solubility is selected for the water-swellaable, water-insoluble polymer component of the hydrogel, and erosion is tailored with other ingredients, not only based on solubility.

**The following rejection has been discussed in the previous office action, and is maintained for reasons of record:**

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-59 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for a composition comprising (1) a hydrogel comprising a water swellable polymer and a blend of a hydrophilic polymer with a complimentary oligomer capable of hydrogen bonding to said hydrophilic polymer and (2) a backing member comprised of a polymer composition that erodes in a moist environment at a slower rate than the hydrogel. Based on the instant disclosure, it is the examiner's position that Applicants do not describe this invention in such a manner that would enable one of ordinary skill in the art to practice this invention without undue burden. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). These include: (1) breadth of the claims; (2) nature of the invention; (3) state of the prior art; (4) amount of direction provided by the inventor; (5) the level of predictability in the art; (6) the existence of working examples; (7) quantity of experimentation needed to make or use the invention based on the content of the disclosure; and (8) relative skill in the art. All of the factors have been considered with regard to the claim, with the most relevant factors discussed below:

**The breadth of claims:** The instant claims 1-59 are directed to a composition comprising (1) a hydrogel comprising a water swellable polymer and a blend of a

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hydrophilic polymer with a complimentary oligomer capable of hydrogen bonding to said hydrophilic polymer and (2) a backing member comprised of a polymer composition that erodes in a moist environment at a slower rate than the hydrogel. It is the examiner's position that this claim, as currently presented, is not supported by the instant specification.

**The nature of the invention:** Like the instant claim set, the instant invention is directed to a composition comprising (1) a hydrogel comprising a water swellable polymer and a blend of a hydrophilic polymer with a complimentary oligomer capable of hydrogen bonding to said hydrophilic polymer and (2) a backing member comprised of a polymer composition that erodes in a moist environment at a slower rate than the hydrogel. As set forth on pages 11-24, the hydrogel-based composition can comprise a multitude of polymers and active agents. Although Applicant discloses numerous polymers and active agents, there is nothing in the specification suggesting that any combination of water-swellaable polymers (pages 13-15), hydrophilic polymers (pages 16-17), complimentary oligomers (pages 18-20), and active agents (pages 20-26) is capable of eroding at a slower rate than the hydrogel. Moreover, since the backing member can be the same polymer as the hydrogel, one of skill in the art would be faced with undue experimentation in formulating a hydrogel/backing member composition wherein the backing member erodes at a slower rate than the hydrogel. This problem is identified by Applicant on page 30, paragraph 00114. Specifically, the situation where Eudragit is used as both the water-swellaable polymer and the backing member is probed. However, this section of the disclosure does not address the situation where

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the backing member and water-swellaable polymers are compounds other than Eudragit. Additionally, paragraph 00114 does not account for the other elements of the hydrogel composition, such as the hydrophilic polymer, complimentary oligomer, and active agent.

Since, as set forth in the instant Claim 1, the water-swellaable-polymer and backing member are not specifically defined, one of skill in the art would not have the ability to formulate a composition comprising any hydrogel together with any polymeric backing member wherein said backing member is capable of eroding at a slower rate than said hydrogel.

**The amount of direction provided by the inventor:** There is nothing in the specification that would indicate that the current invention is capable of working with any water-swellaable polymers, hydrophilic polymers with complimentary oligomers, active agents, and backing members. Moreover, viewed in light of the instant specification, one of ordinary skill in the art would not have the ability to produce hydrogel compositions and backing members wherein said backing member erodes at a slower rate than said hydrogel. There is nothing in the instant specification that details the time it takes for a given hydrogel composition to erode. Given the number of possible water-swellaable polymers, hydrophilic polymers with complimentary oligomers, and active agents disclosed in the instant specification, one of ordinary skill in the art would not have the ability to formulate a hydrogel-based composition capable of eroding in a set amount of time. The same principle applies to the backing member. That is, there are

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no teachings in the instant specification that indicate that a particular backing member is capable of eroding in a moist environment in a specified amount of time.

In short, guidance for preparing a composition comprising a (1) a hydrogel comprising a water swellable polymer and a blend of a hydrophilic polymer with a complimentary oligomer capable of hydrogen bonding to said hydrophilic polymer and (2) a backing member comprised of a polymer composition that **erodes in a moist environment at a slower rate than the hydrogel** is not provided in the specification.

As a result, one of ordinary skill in the art would have to revert to trial and error experimentation in order to practice the invention commensurate in scope with the instant claim set. With respect to the instant composition, there is a substantial gap between a composition comprising a specific combination of hydrogel and backing member agents and one comprising any and all hydrogel and backing member agents. Consequently, a burdensome amount of research would be required by one of ordinary skill in the art to bridge this gap.

**The presence or absence of working examples:** There are three examples set forth in the instant specification, none of which teach the erosion times of hydrogels and backing members in moist environments. As such, based on the instant disclosure, one of ordinary skill in the art would not have the ability to make/use the invention commensurate in scope with the claims without undue experimentation.

**The quantity of experimentation:** In the instant case, there is a substantial gap between a composition comprising a specific combination of hydrogel and backing member agents and one comprising any and all hydrogel and backing member agents.



Consequently, a burdensome amount of research would be required by one of ordinary skill in the art to bridge this gap. In order to utilize the invention as claimed, the skilled artisan would be presented with an unpredictable amount of experimentation. The instant disclosure is broad and generic. It is not clear what specific embodiments would be required in order for one of ordinary skill in the art at the time the invention was made to practice the instant invention commensurate in scope with the claims.

**The relative skill of those in the art:** the skill of one of ordinary skill in the art is very high, e.g., Ph.D. and M.D. level technology.

### ***Response to Arguments***

5. Applicant's arguments filed 08/22/2006 have been fully considered but they are not persuasive.

Applicants argue that the enablement requirement is met if the description enables any mode of making and using the invention because the hydrogel can be assumed known at the time, its composition already decided upon, and thus its erosion rate can be readily measured or assessed qualitatively. All that is needed to practice the invention at that point is to find some polymer having slower erosion and otherwise suitable for use in the backing member and the specification lists a number of classes of suitable polymers (pp. 29-31). Many of them come in grades, as the Eudragits do. Many of them can be plasticized, potentially affecting erodibility. The specification specifically discusses Eudragits. The specification describes some ways, such as solubility control, by which a suitable Eudragit-containing composition that erodes more slowly than a

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given hydrogel can be obtained. Eudragit backing members will, for many applications, be sufficient to practice the invention. They can be used not only where the hydrogel also contains acrylic polymers, but also more broadly.

Even if for some reason, the person of skill in the art elected not to use a Eudragit polymer for the backing member, and chose instead to use a different class of polymer as recited in certain dependent claims, it would in general take only routine experimentation to find a suitable polymer within the class. The experimentation is routine because it is seeking to achieve a desired value for a single variable - the speed of erosion. The experimentation is not seeking to optimize that variable or to achieve extreme values of that variable in an inhospitable environment, but reasonable values in a moist environment - the erosion time of the hydrogel would not be expected to be extreme (at least in a drug delivery application). The experimenter is also not seeking a specific value for the variable, but rather a composition with a rate of erosion that falls somewhere within the broad range that is slower than the (known) rate of erosion for the hydrogel containing the active. Furthermore, one of ordinary skill in the art would be aware of a variety of ways in which the speed of erosion can be affected - either positively or negatively. Notably, erodibility is correlated with water solubility, as explained in the application itself. A solubility limitation has been added now to claim 1 in recognition of this correlation. It is likely that water solubility will already be known in a commercially available polymer. Erodiability can be affected through blending and additives as explained in the application at paragraph [00114]. The experimenter can also affect erodibility through such parameters as the density of the backing member

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and the choice of crystallinity, molecular weight, and degree of crosslinking of the polymer or polymers of which it is made. In addition, as the Examiner has noted (Office Action at 10), the level of skill in this art tends to be quite high. For all of these reasons, no more than routine experimentation would be needed to practice the invention. The Examiner has rejected as non-enabled not just claim 1 but also dependent claims such as claim 15. Claim 15 requires that both the backing member and the water-swellaable, water-insoluble polymer comprise acrylate polymers. The Eudragits are believed to be widely used and representative types of acrylate polymers. The Examiner has noted in the Office Action (p. 8) the existence of a discussion in the specification relating to the situation where Eudragits are used in both the backing member and the water-swellaable, water-insoluble polymer. The Examiner has not pointed to any inadequacies in that discussion. Thus, the Examiner has not pointed to any reason why claim 15 would not be enabled.

In response to this argument, it is argued that specification does not disclose how to make the erodible backing member to satisfy the requirement under U.S.C. 112 first paragraph. The specification does not enable one skilled in the art to make erodible backing without undue experimentation because the materials used to make the backing materials do not having aqueous solubility as required by the claims. The polymers used for the backing member are disclosed as water-insoluble polymers, and used in the water-swellaable, water-insoluble component of the hydrogel. The erosion of these polymers, according to applicants' disclosure on paragraph 00114, are tailored by

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other ingredients and not only a property of the selected water-insoluble polymer.

Therefore, undue experimentation becomes the burden of the skilled artisan to tailor the erosion of the water-insoluble polymers to achieve erosion of the backing member slower than the hydrogel in an aqueous environment as required by the claims. Further, how the erosion of the backing member will be tailored if the different polymer is in the hydrogel? The skilled artisan has to go through trial and error to practice the invention. The specification does not show how to make and use the claimed invention.

### ***Conclusion***

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Isis A Ghali  
Primary Examiner  
Art Unit 1615

IG

*Isis Ghali*

